

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS PO Box 1450 Alcassedan, Virginia 22313-1450 www.emplo.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---------------|----------------------|---------------------|------------------|
| 10/565,239 | 01/19/2006 | Hiroshi Kase | 00005.001285. | 9168 |
| 7590 03022010 FTTZPATRICK CELLA HARPER & SCINTO 1290 Avenue of the Americas | | | EXAMINER | |
| | | | PIHONAK, SARAH | |
| NEW YORK, | NY 10104-3800 | | ART UNIT | PAPER NUMBER |
| | | | 1627 | • |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 03/02/2010 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief

| Application No. | | Applicant(s) | |
|-----------------|---------------|--------------|--|
| | 10/565,239 | KASE ET AL. | |
| | Examiner | Art Unit | |
| | SARAH PIHONAK | 1627 | |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 February 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. 1. X The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods: a) The period for reply expires 4 months from the mailing date of the final rejection. b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). NOTICE OF APPEAL

| 2. The Notice of Appeal was filed on A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of |
|--|
| filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since |
| Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a). |
| AMENDMENTS |

and the second second in the second s

| 3. The proposed aniendinent(s) med after a final rejection, but prior to the date of filling a brief, will <u>not</u> be entered | Decause |
|--|-------------------|
| (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below); | |
| (b) ☐ They raise the issue of new matter (see NOTE below); | |
| (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying | g the issues for |
| appeal; and/or | |
| (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims. | |
| NOTE: (See 37 CFR 1.116 and 41.33(a)). | |
| The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendmen | t (PTOL-324). |
| 5. Applicant's reply has overcome the following rejection(s): | |
| 6. 🔲 Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendm | ent canceling the |
| non-allowable claim(s). | |
| 7. 🔀 For purposes of appeal, the proposed amendment(s): a) 🔲 will not be entered, or b) 🔀 will be entered and an | explanation of |
| how the new or amended claims would be rejected is provided below or appended. | |
| The status of the claim(s) is (or will be) as follows: | |
| Claim(s) allowed: | |
| Claim(s) objected to: | |
| Claim(s) rejected: 1.8.9 and 53-58. | |
| Claim(s) withdrawn from consideration: | |
| AFFIDAVIT OR OTHER EVIDENCE | |
| The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will pecause applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence | |
| because applicant lanea to provide a showing or good and sufficient reasons why the anidavitor other evidence | is necessary and |

was not earlier presented. See 37 CFR 1.116(e).

9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. X The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. The request for reconsideration has been considered but does NOT place the application in condition for allowance because:

| | See Continuation. |
|---------------|---|
| 12. 🔲 | Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). |
| 13. \square | Other: |

/SREENI PADMANABHAN/ Supervisory Patent Examiner, Art Unit 1627

IS P / Examiner, Art Unit 1627 Applicant's response, filed on 2/18/2010, does not place the application in condition for allowance because of the following reasons: Greenlee et. al. teaches that the combination of an adenosine receptor antagonist and a selective serotonin requise inhibitor such as fluoxetine is beneficial for treating depression, while Shimada et. al. teaches that the adenosine receptor antagonist, (E)-8-(3.4-dimethoxystyry)-1,3-diethy-1-methy-3,7-dihydro-11-purine-2-6-dione is beneficial for treating depression. Therefore, one of ordinary skill in the art would have been motivated to combine the adenosine receptor antagonist taught by Shimada et. al. with fluoxetine, with the expectation of success. The Applicants' have amended the claims to include specific dosage ranges, and have burnited a Declaration which shows a synergistic combination with (E)-8-(3.4-dimethoxystyry)-1,3-diethy-1-methy-3,7-dihydro-11-purine-2-6-dione and the selective serotonin reuptake inhibitors, paroxetine hydrochloride. However, these results are still not commensurate in scope with the claims, as the claims are drawn to a combination of (E)-8-(3.4-dimethoxystyry)-1,3-diethyl-7-methy-3,7-dihydro-14-purine-2-6-dione and any selective serotonia reuptake inhibitor, and not just paroxetine and fluoxetine. Additionally, the Applicants have shown synergistic data regarding only two different dosages of (E)-8-(3.4-dimethoxystyry)-1,3-diethyl-7-methyl-3,7-dihydro-14-purine-2-6-dione with paroxetine and fluoxetine, the claims are drawn to a much broader concentration ranks have not demonstrated synergy for the broader dosage range as claimed, the claims are not fully commensurate in scope with the data provided. As such, the reidection under 52 USC 103/a) was proper and is maintained, for response of records.